

Patrick L. Rocco (PR-8621)
Lee S. Shalov
Ralph M. Stone
Jennifer A. Sullivan (JS-6957)
SHALOV STONE & BONNER LLP
163 Madison Avenue
P.O. Box 1277
Morristown, NJ 07962
Tel: (973) 775-8997
Fax: (973) 775-8777
-and-
485 Seventh Avenue, Suite 1000
New York, NY 10018
Tel: (212) 239-4340
Fax: (212) 239-4310

VIANALE & VIANALE LLP
Kenneth J. Vianale
Julie Prag Vianale
5355 Town Center Road, Suite 801
Boca Raton, FL 33486
Tel: (561) 391-4900
Fax: (561) 368-9274

Attorneys for Plaintiff

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JAY WASSERMAN, on behalf of himself and all)
others similarly situated,)

Plaintiff,)

v.)

GENTA, INC., RAYMOND F. WARRELL, JR.,)
and LORETTA M. ITRI,)

Defendants.)

**CLASS ACTION COMPLAINT
AND DEMAND FOR JURY TRIAL**

Plaintiff makes the following allegations, except as to allegations specifically pertaining to him, based upon his counsel's investigation, which included analysis of publicly-available news articles and reports, conference calls, public filings, press releases and other matters of public record.

NATURE OF THE ACTION

1. This is a class action on behalf of all purchasers of the common stock of Genta, Inc. ("Genta" or the "Company") between September 10, 2003 and May 3, 2004, inclusive, (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Throughout the Class Period, defendants issued materially false and misleading statements, artificially inflating the market price of the Company's shares. Specifically, defendants misrepresented the safety of the Company's drug, Genasense, which was being developed to treat advanced melanoma, the most deadly form of skin cancer.

3. Genta conducted a Phase III drug trial comparing Genasense plus dacarbazine with dacarbazine alone as the first line chemotherapy for metastatic melanoma. Throughout the Class Period, defendants falsely represented to the investing public that Genasense did not appear to be associated with serious adverse reactions. Defendants knew that contrary to their representations, however, the use of Genasense was associated with increased toxicity and discontinuations due to adverse event experiences during the trial. Defendants further knew that FDA approval of Genasense was unlikely because the increased toxicity and adverse event experiences outweighed Genasense's marginal benefits. Specifically, defendants knew that:

- (a) 69 patients discontinued therapy for adverse events on the Genasense arm versus 39 patients who discontinued therapy for adverse events on the dacarbazine arm;

- (b) the rate of serious adverse events on the Genasense arm was 40% versus 27% on the dacarbazine arm;
- (c) all toxicities were more frequent on the Genasense arm;
- (d) the frequency of grade 3-4 adverse events, serious adverse events and treatment emergent events leading to discontinuation were all higher on the Genasense arm;
- (e) the incidence of thrombocytopenia was 28.8% in the Genasense arm compared with 11.1% in the dacarbazine arm;
- (f) pyrexia was three times as frequent on the Genasense arm, as compared to the dacarbazine arm;
- (g) neutropenia and anorexia were twice as frequent with Genasense;
- (h) upper extremity thrombosis occurred in 5% of the patients on Genasense as compared with 0.8% of the patients on dacarbazine alone;
- (i) 18.6% of patients who were receiving Genasense permanently discontinued treatment as compared with 10.8% of those patients taking dacarbazine alone.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331, 1337 and 1367 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

5. This action arises under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. § 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

6. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b) and (c). Substantial acts in furtherance of the alleged fraud and/or

its effects have occurred within this District. In addition, defendant Genta is headquartered in Berkeley Heights, New Jersey, within this District.

7. In connection with the acts and omissions alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, the Internet, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

8. Plaintiff purchased Genta common stock during the Class Period, as set forth in the accompanying certification which is incorporated herein by reference, and was damaged thereby.

9. Defendant Genta is a biopharmaceutical company dedicated to the identification, development and commercialization of novel drugs for cancer and related diseases.

10. The individual defendants, at all times relevant to this action, served in the capacities listed below and received substantial compensation:

<u>Name</u>	<u>Position</u>
Raymond P. Warrell, Jr, M.D.	Chief Executive Office and Chairman of the Board of Directors
Loretta M. Itri, M.D.	Chief Medical Officer and President, Pharmaceutical Development

11. The Individual Defendants, as senior officers and/or directors of Genta, were controlling persons of the Company. Each exercised their power and influence to cause Genta to engage in the fraudulent practices complained of herein.

12. Each of the defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Genta common stock, by disseminating

materially false and misleading statements and/or concealing material adverse facts. In carrying out the scheme defendants: (i) deceived the investing public regarding Genta's business, its finances and the intrinsic value of Genta common stock; and (ii) caused plaintiff and other members of the Class to purchase Genta common stock at artificially inflated prices.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

13. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all persons who purchased or otherwise acquired Genta common stock between September 10, 2003 and May 3, 2004, inclusive, and who were damaged thereby. Excluded from the Class are defendants, members of the immediate family of each of the Individual Defendants, any subsidiary or affiliate of Genta and the directors, officers and employees of Genta or its subsidiaries or affiliates, or any entity in which any excluded person has a controlling interest, and the legal representatives, heirs, successors and assigns of any excluded person.

14. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are thousands of members of the Class located throughout the United States. As of March 11, 2004, there were reportedly more than 77 million shares of Genta common stock outstanding. Throughout the Class Period, Genta common stock was actively traded on the NASDAQ Stock Market (an open and efficient market) under the symbol "GNTA." Record owners and other members of the Class may be identified from records maintained by Genta and/or its transfer agents and may be notified of the

pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

15. Plaintiff's claims are typical of the claims of the other members of the Class as all members of the Class were similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

16. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

17. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- (a) whether the federal securities laws were violated by defendants' acts and omissions as alleged herein;
- (b) whether defendants participated in and pursued the common course of conduct complained of herein;
- (c) whether documents, press releases, and other statements disseminated to the investing public and the Company's shareholders during the Class Period misrepresented material facts about the business, finances, financial condition and prospects of Genta;
- (d) whether statements made by defendants to the investing public during the Class Period misrepresented and/or omitted to disclose material facts about the business, finances, value, performance and prospects of Genta;

- (e) whether the market price of Genta common stock during the Class Period was artificially inflated due to the material misrepresentations and failures to correct the material misrepresentations complained of herein; and
- (f) the extent to which the members of the Class have sustained damages and the proper measure of damages.

18. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this suit as a class action.

SUBSTANTIVE ALLEGATIONS

19. The Class Period begins on September 10, 2003. On that date, in a press release entitled "Genta and Aventis Report Positive Results in Phase 3 Trial of Genasense™ Plus chemotherapy in Patients with Advanced Malignant Melanoma," Genta announced the results of the Phase 3 clinical study of Genasense™. In that press release Genta stated:

- Analysis of all patients on an intent-to-treat (ITT) basis showed that the addition of Genasense to dacarbazine resulted in a median survival of 9.1 months, compared with 7.9 months for patients treated with dacarbazine alone ($p=0.184$)
- For patients treated per -protocol who have completed a minimum follow-up of 12 months ($n=480$), the addition of Genasense resulted in a median survival of 10.1 months compared with 8.1 months for dacarbazine alone ($p=0.035$).

- For the ITT Population (n=771), patients treated with Genasense plus dacarbazine showed a significant increase in median progression-free survival to 78 days, compared with 49 days for patients treated with dacarbazine alone (P=0.001)
- For the ITT population (n=771), patients treated with Genasense plus dacarbazine achieved an antitumor response rate of 11.7% (using RECIST criteria), compared with 6.8% for patients treated with dacarbazine alone (P=0.019).
- The addition of Genasense to dacarbazine did not appear to be associated with serious, previously unreported adverse reactions compared with the use of dacarbazine alone.

20. In the same press release, Defendant Itri is quoted as stating: "These results have been observed in a disease that is notoriously unresponsive to standard therapy and for which no drug has shown a survival advantage. We believe the current data support the NDA submission we have initiated using provision granted under 'Fast Track' designation for Genasense." For the reasons set forth in paragraph 3, these statements were false and misleading.

21. In a conference call conducted on September 10, 2003 to discuss the results of the Genasense Phase 3 clinical trials, defendant Wardell stated in response to a question regarding adverse events that "The safety profile is characterized by certain kinds of common reactions. The most common is a low grade fever. That usually appears in the first and second day and then goes away, really, without any therapy. No one, to my knowledge, has ever had to drop out of the program due to fever." For the reasons set forth in paragraph 3 above, this statement was materially false and misleading.

22. On December 8, 2003, Genta completed its new drug application to the FDA for Genasense. On February 6, 2004, Genta announced that the FDA had accepted the new drug application and that the FDA had granted the application priority review status. At that time, defendant Itri stated that "This New Drug Application represents the first clinical indication for a drug that promotes chemotherapy induced apoptosis, the first systemic use of an antisense therapy, and potentially the first new drug for patients with advanced melanoma in almost 30 years." For the reasons set forth in paragraph 3 above, this statement was false and misleading.

23. On February 11, 2004, during a conference call with analysts, defendant Wardell stated: "We believe the application as submitted is approvable as is. Other than the routine safety update in April, we have no plans to re-analyze the efficacy [in the submission] during the review period unless specifically requested by the agency...Safety data shows a modest increase in the neutropenia and fever [which] appears quite acceptable from an oncology point of view." For the reasons set forth in paragraph 3 above, this statement was false and misleading.

24. On March 12, 2004, Genta filed its Form 10K for the year ended December 30, 2003. In the 10K Genta stated with respect to the Phase 3 clinical trial results: "The addition of Genasense™ to dacarbazine did not appear to be associated with serious, previously unreported adverse reactions compared with the use of dacarbazine alone." For the reasons set forth in paragraph 3, this statement was false and misleading.

25. On April 30, 2004, the staff of the Oncologic Drugs Advisory Committee (ODAC) of the FDA stated in briefing materials in advance of the May 3, 2004 ODAC meeting that the Phase 3 clinical trial of Genasense failed to demonstrate a survival benefit, which was the primary trial endpoint. However, small but unreliable benefits were seen for progression-free survival (PFS) and

response rates (RR). The staff also stated: "[u]ncertainty also exists regarding whether an improvement in PFS and RR of this magnitude outweighs the increase in toxicity seen with the combination [of Genasense and dacarbazine.] ... Survival was not improved and toxicity was increased." As a result of this announcement, the price of Genta shares dropped \$5.83 or 40.4% to close at \$8.60 on the NASDAQ stock market on exceptionally high volume of over 30 million shares traded.

26. On May 3, 2004, the ODAC ruled by a 13-3 vote that, in the absence of increased survival, the evidence presented did not provide substantial evidence of effectiveness to outweigh the increased toxicity of Genasense. As a result of this announcement, the price of Genta shares fell more than \$3 per share, to close at \$5.11 on May 3, 2004, with over 17 million Genta shares traded that day, another exceptionally high volume day.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:
FRAUD-ON-THE-MARKET DOCTRINE**

27. At all relevant times, the market for Genta common stock was an efficient market for the following reasons, among others:

- (a) Genta common stock met the requirements for listing, and was listed and actively traded, on the NASDAQ Stock Market, an efficient securities market;
- (b) As a regulated issuer, Genta filed periodic public reports with the SEC;
- (c) Genta stock was followed by securities analysts employed by major brokerage firms who wrote reports which were distributed to sales forces and certain customers of their respective brokerage firms.

(d) Genta regularly issued press releases which were carried by national newswires.

Each of these releases was publicly available and entered the public marketplace.

28. As a result, the market for Genta securities promptly digested current information with respect to Genta from all publicly-available sources and reflected such information in Genta's stock price. Under these circumstances, all purchasers of Genta common stock during the Class Period suffered similar injury through their purchase of stock at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR

29. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. The specific statements pleaded herein were not identified as "forward-looking statements" when made. Nor was it stated with respect to any of the statements forming the basis of this complaint that actual results "could differ materially from those projected." To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking was made the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Genta who knew that those statements were false when made.

SCIENTER ALLEGATIONS

30. As alleged herein, defendants acted with scienter in that defendants knew that the public documents and statements, issued or disseminated by or in the name of the Company were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding Genta and its business practices, their control over and/or receipt of Genta's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Genta were active and culpable participants in the fraudulent scheme alleged herein. Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information which they caused to be disseminated to the investing public.

31. The Individual Defendants participated in creating, editing, and reviewing the quarterly safety reports to the FDA detailing adverse events experienced by patients in the trials. They are sophisticated medical professionals who understood the implications of reports they received about the medical studies conducted. As a result, the defendants knew or recklessly disregarded the fact that their representations about the safety of Genasense were materially misleading

COUNT I

**Violations Of Section 10(b) Of The
Exchange Act And Rule 10b-5 Promulgated
Thereunder Against All Defendants**

32. Plaintiff repeats and realleges each and every allegation contained above.

33. Each of the defendants: (a) knew or recklessly disregarded material adverse non-public information about Genta's financial results and then existing business conditions, which was not disclosed; and (b) participated in drafting, reviewing and/or approving the misleading statements, releases, reports and other public representations of and about Genta.

34. During the Class Period, defendants, with knowledge of or reckless disregard for the truth, disseminated or approved the false statements specified above, which were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

35. Defendants have violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder in that they: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon the purchasers of Genta stock during the Class Period.

36. Plaintiff and the Class have suffered damage in that, in reliance on the integrity of the market, they paid artificially inflated prices for Genta stock. Plaintiff and the Class would not have purchased Genta stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' false and misleading statements.

COUNT II

**Violation Of Section 20(a) Of The Exchange Act
Against Individual Defendants**

37. Plaintiff repeats and realleges each and every allegation contained above.

38. The Individual Defendants acted as controlling persons of Genta within the meaning of Section 20(a) of the Exchange Act. By reason of their senior executive and/or Board positions they had the power and authority to cause Genta to engage in the wrongful conduct complained of herein.

39. By reason of such wrongful conduct, Genta and the Individual Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Genta stock during the Class Period.

WHEREFORE, plaintiff prays for relief and judgment, as follows:

1. Determining that this action is a proper class action and certifying plaintiff as class representative under Rule 23 of the Federal Rules of Civil Procedure;

2. Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

3. Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

4. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

DATED: May 6, 2004

SHALOV STONE & BONNER LLP

By: Patrick L. Rocco /ms
Patrick L. Rocco (PR-8621)
Jennifer A. Sullivan (JS-6957)

163 Madison Avenue
P.O. Box 1277
Morristown, NJ 07962
Tel: (973) 775-8997
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-and-

Lee S. Shalov
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485 Seventh Avenue, Suite 1000
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5355 Town Center Road, Suite 801
Boca Raton, FL 33486
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Fax: (561) 368-9274

Attorneys for Plaintiff

Vianale & Vianale LLP
 5355 Town Center Road, Suite 801
 Boca Raton, FL 33486
 Tel: 561-391-4900 / Fax: 561-368-9274

**CERTIFICATION OF PLAINTIFF
 PURSUANT TO FEDERAL SECURITIES LAWS**

Re: GENTA INC. (NASDAQNM: GNTA)

I, JAY WASSERMAN hereby declare:

1. I have reviewed the complaint and authorized its filing. I retain the law firm of Vianale & Vianale LLP and such co-counsel it deems appropriate to associate with to pursue such action on a contingent fee basis.

2. I did not purchase the security that is the subject of this action at the direction of counsel or in order to participate in this private action or any other litigation under the federal securities laws.

3. I am willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.

4. I have made no transaction(s) during the Class Period in the debt or equity securities that are the subject of this action except those set forth below: (use a separate sheet if necessary)

Date	Transaction Type	# of Shares	Price
See attachment "A"			

5. During the three years prior to the date of this Certificate, I have sought to serve or served as a representative party for a class in the following actions filed under the federal securities laws:

N/A

6. I will not accept any payment for serving as a representative party on behalf of the class beyond a pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 5 day of May, 2004.

Signed: Jay Wasserman

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ATTACHMENT "A"

Date	Buy/Sell	No. Of Shares	Price Per Share
Jay Wasserman Account			
11/29/01	Buy	130	\$16.00
11/30/01	Buy	900	\$15.95
12/5/01	Buy	500	\$16.50
5/8/03	Buy	2,000	\$8.41
5/15/03	Buy	200	\$10.18
5/15/03	Buy	800	\$10.18
6/17/03	Buy	500	\$13.40
6/17/03	Buy	1,000	\$13.40
6/17/03	Buy	200	\$13.40
6/17/03	Buy	300	\$13.40
1/21/04	Buy	200	\$11.20
1/21/04	Buy	300	\$11.20
1/21/04	Buy	500	\$11.20
Jay Wasserman and Deborah Wasserman Joint Account			
11/7/03	Buy	3,000	\$9.70
11/26/03	Buy	2,500	\$10.10
1/22/04	Buy	2,000	\$12.46
1/23/04	Buy	2,000	\$13.17
2/6/04	Buy	3,500	\$13.73
2/19/04	Buy	1,500	\$11.70
Jay Wasserman IRA Account			
12/2/03	Buy	3,000	\$11.00
12/2/03	Buy	500	\$11.00